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Towards Patent Pools in Biotechnology?

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Abstract

We analyze the extent to which patent pools (agreements where patent holders agree to license their intellectual property as a package) could be used as an institution to facilitate technology transactions in biotechnology. Patent pools have been used with success in the consumer electronics and other sectors but they are untested in biotechnology despite their transaction cost reducing potential. We suggest two explanations for the fact that patent pools have not been used in this industry. The first is that the current antitrust requirements are difficult to meet in biotechnology. The second is the availability of simpler alternatives that will often be more profitable to patent holders: aggregation of rights by one party and cross-licensing.

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1. INTRODUCTION¹

Shortly after the severe acute respiratory syndrome (SARS) outbreak in February 2003, patent applications covering sequences of the genome of the SARS coronavirus have been filed by several research teams around the globe² (Simon et al., 2005). It has been argued that this might result in a complex and uncertain intellectual property situation which could delay the development of SARS vaccines and diagnostic tools (ibid.). The World Health Organization (WHO) SARS consultation group recommended that “a strategy be developed, in consultation with stakeholders, to address potential SARS CoV-related IP issues and thus enhance development of intervention approaches” (WHO, 2004). As a result, the four parties known to own key patent applications³ (CDC) have expressed their willingness to form a patent pool with the goal to enable wide access to the SARS genome (Simon et al. 2005).

This initiative is of particular interest because patent pooling has often been mentioned as a potential solution (e.g. UPSTO 2000, FTC 2002, WHO 2005, WHO 2006⁴) to fragmented intellectual property rights in biotechnology but that idea had never been put in practice. Although the extent of the problem is disputed, fragmented intellectual property rights in biotechnology are both a concern for innovation policy and a practical problem in high profile cases such as SARS, avian influenza and malaria vaccines.

In this paper, we analyze the extent to which patent pools could be used as an institution to facilitate technology transactions in biotechnology when intellectual property rights necessary for the development or commercialization of product are fragmented among different entities. First, we attempt to clarify the notion of patent pools. We then outline a rationale for patent pools in biotechnology based on transaction costs. After that, we review regulatory requirements for patent pools in Europe and in the United States and discuss implications for biotechnology patent pools. Finally, we argue that two alternatives to forming a patent pool are particularly relevant in biotechnology, which may explain why patent pools have never been used in this industry.

¹ I owe special thanks to Dominique Foray and Peter Drahos for helpful suggestions.

² The Bernhardt-Nocht Institut, the British Columbia Cancer Agency, the Centers for Disease Control and Prevention, Erasmus Medical Center and Hong Kong University.

³ These are: the Centers for Disease Control and Prevention (CDC), Health Canada, Coronovative and Versitech. CDC is a branch from the US department of Health and Human Services. Health Canada is Canada’s ministry of health, Coronovative is a spinoff from Erasmus Rotterdam University and Versitech is the technology transfer office from Hong Kong University.

⁴ WHO (2006:68) concludes that “Patent pools of upstream technologies may be useful in some circumstances to promote innovation relevant to developing countries. WHO and WIPO should consider playing a bigger role in promoting such arrangements”.

1.1 Definition

The term patent pool is not to be found in patent law and is not a term of art⁵. As a result, 'patent pool' can mean different things to different people. Some have in mind a compulsory mechanism that would strike a different balance between rewarding inventors and ensuring access. Consider for example the proposal to form a patent pool for AIDS (Essential Inventions, 2005) where holders of patents essential to the manufacture of antiretrovirals would be invited to join the pool and to accept capped royalties; should they decline, compulsory licenses would be sought⁶. On the other hand, Resnik (2003) has proposed a (unique) biotechnology patent pool where participation would be voluntary and that would operate like collective rights management associations for copyrighted music.

In this paper we do not discuss patent pools where participation would not be voluntary or patent pools as collective right management because these would imply significant changes in the patent system. Rather, we restrict our attention to patent pools as a mechanism that is applicable in the current legal environment. We shall thus adopt the following definition:

"The notion of technology pools covers agreements whereby two or more parties agree to pool their respective technologies and license them as a package."

That definition comes from the guidelines of the European Commission on the application of the Article 81 of the EC Treaty to technology transfer agreements (hereafter 'EC guidelines') (European Commission, 2004) but a similar one can be found in the US Antitrust Guidelines for the Licensing of Intellectual Property (hereafter 'US guidelines') (US DOJ and FTC, 1995):

"Cross-licensing and pooling arrangements are agreements of two and more owners of different items of intellectual property to license one another or third parties."

At this point it may be helpful to clarify the difference between cross-licensing and patent pooling arrangements. In the context of that paper the distinction will be that cross-licensing agreements focus on reciprocal access to intellectual property rights while patent pool focus on (package) licensing to third parties.

1.2 Recent practice

Despite the recent interest in patent pools, they remain a relatively rare occurrence. For instance in the last decade only four pools have solicited and obtained business reviews from the US Department of Justice⁷ (others may be pending). These four pools (MPEG-2 pool, the 3G platform and the two DVD

⁵ As the US Supreme Court put in *United States v. Line Materials*, 333 U.S. 287, 313 n.24 (1948), noted by Klein (1997).

⁶ Admittedly, this would bear some resemblance with the well-known patent pool formed in 1917 to enable the wartime manufacture of aircraft under the instigation of US Secretary of Navy Franklin Roosevelt (both attempting to address an international crisis).

⁷ Business reviews letters are statements by the Department of Justice on its current antitrust enforcement intentions with respect to a particular practice.

pools) are the best known and have been well documented elsewhere⁸ but it is interesting to make a couple of observations on what they have in common:

Technologies covered. All four abovementioned pools are in the electronics/video content industry, they are all intimately linked to a technical standard, they were at the time of the formation emerging technologies that are now dominant (with the exception of the most recent, 3G, that has not yet become mainstream).

Membership. The pool members/licensors are usually large vertically integrated firms (Toshiba, Philips, Sony...). Membership is open to anyone who wants to join and an external review process is in place to determine whether patents considered for inclusion in the pool are valid and essential to the standard.

Licensing terms. The licensing terms are typically standard, publicly disclosed, non-discriminatory, open to anyone who wants to license and fairly linear with small up-front fees. The licensing terms are designed for specific types of consumer goods such as a MPEG-2 decoding product, a DVD player, a DVD recorder, a DVD disc...

Thus, the modern patent pool has so far been an institution closely linked to a technical standard and designed to facilitate technology licensing on a large scale. The MPEG-2 patent pool provides an excellent illustration with a total of 790 patents (134 families) owned by 24 different licensors and more than thousand licensees⁹. It is also interesting to note that a few other pools have been formed (IEEE 394, DVB-T, AVC/H.264, MPEG-4,...) and that they share the same features as those outlined above.

1.3 Other interesting types of pools

It is important to take into account that new types of pools may emerge that need not conform to the practice described in the last paragraph (although such new types may raise fresh antitrust issues). Consider the differences between the SARS patent pool brought up in the introduction and the consumer electronics pools. The SARS patent pool will not be in an industry characterized by all-important network effects or be closely linked to a standard. For the moment, the licensors are not vertically integrated firms but universities and public institutions¹⁰ and there will be far fewer licensees. But most importantly the commercial products in which the licensed technology will be embedded do not yet exist and will be developed by the licensees after extensive R&D efforts. Therefore, the licensing policy of the SARS patent pool might be quite different from other modern patent pools.

⁸ See appendix B for a summary of the features of those pools and of number of other pools established recently or in formation.

⁹ According to the web site of the entity operating the MPEG patent pool, <http://www.mpegla.com> accessed 22/04/06.

¹⁰ Thus the pool members can hardly be described as profit maximizers. Another oddity of the SARS patent pool is that the underlying patents were only patent applications when the parties announced their intention to pool. It remains to be seen if a patent pool can be formed before these applications are granted.

Yet another type of patent pools could emerge in the context of research consortiums and other research collaborations. There participants could¹¹ commit *ex ante* to contribute patents resulting from their joint research efforts to the pool. Then the pool could be used by the parties as a tool for the joint management of intellectual property and as a mechanism supporting the exchange of unpatented technical information and know-how between the parties¹². Particularly interesting in this regard is the SNP consortium, a non-profit foundation that discovered 1.5 million SNPs¹³ and made all the related information available to the public without intellectual property restrictions. This initiative was financed by the Wellcome Trust but also by large pharmaceutical firms ranging from Pfizer to GlaxoSmithKline passing by Aventis, AstraZeneca, Novartis, Roche, Bayer, etc. The motivation of the corporate sponsors behind SNP consortium was probably to undermine attempts by biotech tool companies to obtain proprietary positions on SNPs (Agrawal, 2002; Cockburn, 2004). A patent pool with low and nondiscriminatory licensing terms might have achieved similar objectives while at the same time providing some cost-recovery through royalties. In that example, consortium members wanted to expand the public domain for strategic reasons but consortia or research collaborations with other objectives may also find pooling attractive either as a mechanism for the collective management of IPR and/or as an institutionalized mechanism for sharing non-patented information. However, we will not discuss this type of patent pools further as they have a different rationale than the one we will present in the next session.

2. THE RATIONALE FOR PATENT POOLS IN BIOTECHNOLOGY

2.1 The anti-commons in biomedical research

The rationale for patent pools in biotechnology is intricately linked to a problem known as the anti-commons in biomedical research after a famous article by Heller and Eisenberg (1998). Their argument echoes earlier concerns linked with university patenting and the patentability of genomic sequences. However, they stress that the cost of having patents in the early stages of biomedical research lies not only with the standard restrictions that patents place on use but also with specific problems linked with the fragmentation of intellectual property rights. They suggest that when developing a commercial product requires access to multiple patents, negotiating access with different patent owners may be prohibitively difficult and costly. Thus, Heller and Eisenberg conceive ‘a tragedy of the anti-commons’ -with too many property rights leading to under-use of valuable resources- as the mirror image of the tragedy of commons.

The strength of the anticommons thesis rests on two assumptions that are particularly difficult to test: (1) that developing commercial biomedical products requires access to many different IPRs and (2) that negotiating access with different patent owners is indeed prohibitively difficult and costly. On the first point, the number of biotechnology patents has certainly increased dramatically over the last

¹¹ We use the conditional tense as we are not aware of any such arrangements existing and to our best knowledge none is documented in the literature.

¹² That is, sharing know-how and unpatented information would be less sensitive because of the resulting joint ownership of the patents. That point is made in UPSTO (2000).

¹³ SNP stands for Single Nucleotide Polymorphisms, common human genetic variations which are of great value in biomedical research and drug discovery.

decade although that by itself does not necessarily imply greater fragmentation. Walsh et al. (2003) report from interviews with biotechnology industry IP practitioners that preliminary freedom to operate searches can sometimes find hundreds of patents relevant to a candidate product but that on closer inspection “there may be, in a complicated case, about 6-12 that they have to seriously address, but that more typically the number was zero.” There is, however, enough anecdotal evidence to suggest that fragmentation of rights is a serious concern in a significant number of situations in biotechnology.

2.2 Patent pools and transaction costs

In this subsection, we discuss how patent pools may change the repartition and reduce transaction costs when intellectual property rights are fragmented between several entities. A first type of transactions costs lowered by the formation patent is the cost of patent mapping by potential licensees. Firms or other entities considering whether to develop a product need to identify the patents they might need to license in order to obtain freedom to operate. That will usually start by searching databases by keywords which can yield hundreds of patents. For each of these, they need to form a judgment on whether their products would be infringing and if so whether the patent is valid. That is a difficult exercise due to the uncertainty over the breadth and validity of patents inherent to the patent system¹⁴. In other words, identifying important patents in a technological area can entail real resources costs.

The process we describe above is in fact very similar to the independent review that modern patent pools use. In such reviews, an expert evaluates the essentiality and validity of patents that pool members wants to include in the pool. This is done not only to show regulatory authorities that the pool is likely to integrate complementary patent rights but also for marketing reasons as “a license with patents that have not been evaluated by an outside expert will lack credibility and be difficult to sell” (Horn, 2003). What we mean to say is that potential licensees can have a higher presumption that the patents are valid and important if they are included in the pool than otherwise, which lowers the cost of patent mapping. This effect may offset the cost of the review by the pool, especially if the number of potential licensees is large.

Another way through which the patent pool clarifies the patent landscape is that it sends a signal to potential licensees that the patents are available for licence, in principle at non-discriminatory rates¹⁵. That brings us to a second type of transactions costs associated with bargaining over licences and licensing terms.

¹⁴ In the words of Lemley and Shapiro (2005): “The actual scope of a patent right, and even whether the right will withstand litigation at all, are uncertain and contingent questions. This uncertainty is not an accident or mistake. Rather, it is an inherent part of our patent system, an accommodation to the hundreds of thousands of patent applications filed each year, the inability of third parties to participate effectively in determining whether a patent should issue, and the fact that for the vast majority of issued patents, scope and validity are of little or no commercial significance.”

¹⁵ This point is made in Simon (2005): “The formation of such a patent pool would send a powerful signal to putative licensees (e.g. vaccine manufacturers) that patent owners mean to make their IP rights available from standard rates (...).”

Patent pools also have the fairly obvious but important advantage of considerably reducing the number of licences that need to be negotiated. For instance, suppose that there are m licensors and n potential licensees; if each licensee negotiates with each licensor $m \cdot n$ licences need to be negotiated. However, if each licensee negotiates with a pool that includes all licensors that number reduces to n licences¹⁶. Still the modern patent pools in electronics went much further by specifying standard and non-discriminatory terms and by making them publicly known. In addition these terms appear to be ‘take it or leave it’ offers. Thus not only the number of licences goes down but the negotiations become much simpler to the point where they even disappear completely. As pointed out in the second section, biotechnology patent pools will likely be different entities than modern patent pools and they might not go so far in specifying licence terms in advance. Nonetheless at least the benefits associated with less licences to be negotiated will be present.

It is important to realize, however, that it is not because licensees incur no (or reduced) transaction costs that these costs magically disappear. Rather, much of the hard work has already taken place in the negotiations between pool members. In particular, they have agreed on a formula to split the revenues of the pool which is a central element of the pooling arrangement¹⁷. Because patent pools require some sort of agreement between the patent owners on the respective value of their inventions they may encounter the same problems (asymmetries of information, cognitive bias, etc.) that prevent deals to be reached in other types of technology transactions.

In summary, transaction costs with a patent pool tend to be incurred upfront and by the licensors. In that sense, the formation of a pool can be seen as a marketing effort from patent holders. Apart from this important distribution effect, we also believe that patent pools can reduce total transaction costs by simplifying patent landscapes and facilitating technology transactions.

3. THE REGULATORY ENVIRONMENT

Being horizontal agreements between patent owners, patent pools have long aroused the suspicion of competition authorities. The early history of patent pools shows that this suspicion was indeed warranted in some cases¹⁸ but regulators have come to recognize that patents pools can be pro-competitive, starting with the US intellectual property licensing guidelines (1995). Nevertheless, patent pools are still perceived by the biotechnology industry as involving a substantial risk of antitrust litigation (Seide et al. 2001). This is not helped by the fact that the regulations on patent pools contain

¹⁶ Clearly the number of potential licencees may change with a pool, some licensors may be licensees as well and the pool need not include all licensors but the point is clear enough.

¹⁷ Compare with Merges (2001) who identifies the two central principles of a pool as (1) consolidate property rights in a central entity (i.e., the contract); and (2) establish a valuation mechanism to divide up the royalty stream.

¹⁸ Consider for instance the harrows pool that came up in a case before US Supreme Court *E. Bement & Sons v. National Harrow* in 1902. According to Gilbert (2004) “The pool grew to 22 firms accounting for over 90 percent of all manufacturing and sales of float spring tooth harrows in the United States. Each firm was required to adhere to uniform price schedules for the sale of all products manufactured under the National Harrow license. The pool set uniform license terms that fixed prices for licensed products, required that the licensee make or sell only the licensed products, and obligated licensees not to challenge the patents and to defend the patents if challenged by others.”

few safe harbours¹⁹ (Beeney, 2002 ; Janis, 2005) and by the lack of relevant case law. It is thus important for our purposes to discuss the extent to which competition law limits the prospects for biotechnology patent pools²⁰. We outline some key aspects of the relevant regulations in the most important antitrust jurisdictions, the European Union and the United States, and then discuss implications for patent pools in biotechnology.

3.1 Regulatory requirements in Europe

The 2004 guidelines on the application of article of the EC Treaty to technology transfer agreements (“EC guidelines”) is the main source of guidance on the application of competition law to patent pools in Europe. The guidelines recognize that patent pools may be restrictive of competition (EC guidelines §213) but also that they can produce pro-competitive effects, in particular by reducing transaction costs and by setting a limit on cumulative royalties to avoid double marginalization (§214). The key factor used to discriminate between pro- and anti- competitive pools is the nature of the pooled technologies:

- As a general rule, the Commission considers that the inclusion of substitute technologies in a pool constitutes a violation of article 81(1)²¹ (§219).
- Conversely, when the pool is composed only of technologies that are essential, which is defined as having no substitute (§216), the creation of the pool is considered to be pro-competitive (§220).
- If the pool includes complementary, but non essential technologies, the agreement is likely to be caught by Article 81(1) where the pool has a significant position on any relevant market (§221).

Although the Guidelines develop a number of factors to be used to assess technology pools comprising non-essential technologies, these are to be applied only when technologies in the pool become non essential after technological developments (§222) not for the formation of new pools.

Finally a number of guidelines on restraints commonly found in pools are specified. For instance, where the pool has a dominant position on the market, royalties and other licensing terms should be fair and non-discriminatory and licenses should be non-exclusive (§226), licensors and licensees must be free to develop competing products and standards and must be free to grant licenses outside the pool (§227), grant back obligations should be non-exclusive and limited to developments important to the use of the pooled technology (§228).

¹⁹ Safe harbours serve as shortcuts in antitrust analyses to determine whether a particular agreement is pro-competitive.

²⁰ A more comprehensive review would also have to consider the patent misuse defense in the context of biotechnology patent pools [see Gosh and De Shield (2005)] but patent misuse and antitrust violations are very closely related.

²¹ Article 81(1) of the EC treaty prohibits agreements which have as their object or effect the restriction of competition.

3.2 Regulatory requirements in the United States

The 1995 Antitrust Guidelines for the Licensing of Intellectual Property (“US Guidelines”) are less detailed than their European counterparts but a number of business reviews letters from the Department of Justice antitrust division offer additional guidance²². According to the US Guidelines, cross-licensing and pooling arrangements “may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation”. The following practices were deemed to be anticompetitive: collective price or output restraints and, in certain cases, grantbacks, settlements involving cross-licensing between horizontal competitors and exclusion from a pooling arrangement.

In the Sony letter and subsequent letters, the Department of Justice adopted a two step procedure in reviewing the proposed patent pools. It attempted to determine “(i) whether the proposed licensing program is likely to integrate complementary patent rights and (ii), if so, whether the resulting competitive benefits are likely to be outweighed by competitive harm posed by other aspects of the program” (Sony letter). In all four business review letters, the Department of Justice found that the pooled patents were essential (and therefore complementary) in the sense of having no substitutes²³. It thus remains to be seen whether and under what conditions a pool including complementary but non-essential patents would be acceptable.

The first three review letters added other requirements which are summarized in those terms by the USPTO white paper (2000): “(1) the patents in the pool must be valid and not expired (2) no aggregation of competitive technologies and setting a single price for them (3) an independent expert should be used to determine whether a patent is essential to complement technologies in the pool, (4) the pool agreement must not disadvantage competitors in downstream products markets, and (5) the pool participants must not collude on prices outside the scope of the pool, e.g. on downstream products.”

3.3 Implications for patent pools

As should be apparent from the preceding sub-sections, the antitrust analysis of patent pools in both Europe and the United States uses as a central concept the nature of the pooled patents. It is clear that patent pools including substitute technologies are deemed anti-competitive and subject to challenges from competition authorities. On the contrary, patent pools including only essential patents are pro-competitive to the extent that they do not indulge in anticompetitive practices in the dissemination of

²² We will refer to these as the MPEG Letter, the Sony Letter, the Toshiba Letter, and the 3G Letter; see the bibliography for details.

²³ Compare “The Portfolio combines patents that an independent expert has determined to be essential to compliance with the MPEG-2 standard; there is no technical alternative to any of the Portfolio patents within the standard” (MPEG letter), “it appears reasonably likely that the pool will combine only complementary patents for which there are no substitutes for the purpose of compliance with the Standard Specifications” (Toshiba letter) “it appears that the Licensors intend to license through the pool only complementary patents for which there are no substitutes” (Sony letter) “the limitations of patents to those ‘technically’ essential to compliance (...) provide reasonable assurance that patents combined in a single PlatformCo for a 3G radio interface technology will not be substitutes for one another” (3G letter).

the technology²⁴. What is less clear is whether competition authorities would be ready to accept patent pools that include patents meeting a weaker definition of complementary than essentiality or where essentiality is likely but difficult to prove.

The reason why this matters particularly for biotechnology patent pools is twofold. First, biotechnology is characterized by the absence of standards. As several commentators have pointed out, this poses a problem for patent pools since essential patents cannot be defined as those patents necessary to comply with the standard. A solution advocated by Ebersole et al. (2005) in the context of diagnostic generics is the creation of standards to facilitate patent pooling. Elsewhere, Horn (2003) suggests that with a defined field of use the absence of standards need not be of consequence.

Second, in the SARS and avian flu²⁵ cases and perhaps in many technology areas within biomedical research where patent pools would be of most interest, final products have yet to be developed. But when final products do not yet exist it may be *ipso facto* especially difficult to determine which patents are essential. Indeed, the point behind forming a pool may be to reduce uncertainty by ensuring that licensees can have access to all the intellectual property they may need even if it later turns out that they do not need a particular piece of intellectual property.

4. ALTERNATIVES TO POOLING

A strong objection to patent pools in biotechnology is that biotechnology patent owners will not be interested in forming pools. Unfortunately, the traditional literature on patent pools is of little guidance here because it has focused on the conditions under which pools would be pro-competitive and thus agreeable by courts or competition authorities. The fact that a group of patent owners wants to form a pool was thus the starting point of the analysis and not something that needed to be explained or discussed in detail. Indeed a weird result of economic models of patent pools (Shapiro 2001; Choi 2002; Lerner and Tirole 2004; Sung-Hwan 2004; Aoki and Nagaoka 2004; Lerner, Tirole and Strojwas 2005) is that patent owners almost invariably want to pool if they are allowed to, the exception being that sometimes an essential patent owner can obtain a stronger bargaining position by waiting to enter the pool.

Our argument will be that to meaningfully discuss whether patent owners will be interested in forming patent pools in biotechnology, it is important to consider not only pooling versus non-exclusive licensing but also other counterfactuals and in particular pooling versus the aggregation of the relevant rights by one entity and pooling versus cross-licensing.

²⁴ And, to a lesser extent, that they are open to third parties that would like to join.

²⁵ Which we discuss elsewhere in the paper. See section 1 and annex A.

4.1 Aggregation of rights by one entity as an alternative to pooling

Economic papers on patent pools have always assumed that aggregation of rights by one entity²⁶ was not possible. In fact, doing otherwise might have resulted in trivial results only. Moreover, this assumption was entirely legitimate in the context of the consumer electronics pools because the patent owners were typically large manufacturing firms. Exclusive licensing deals between horizontal competitors with significant market shares are unlikely to meet antitrust requirements but even if they could it is implausible that large manufacturers firms would be ready to leave the market in exchange for royalty payments.

However, in the biotechnology industry many important patents are owned by universities or specialized research firms that do not have full development much less production capabilities. As a consequence, they are more than happy to grant exclusive licenses and such exclusive licenses are not likely to be challenged by antitrust authorities because they do not suppress competition that may have existed without the exclusive license (as may be the case between two vertically integrated firms).

Thus, in biotechnology the aggregation of rights by one entity can at least in a number of cases be a simple alternative to pooling as a solution to fragmented patent rights. Appendix A illustrates this point with an example of a patent thicket resolved by the aggregation of rights by one patent owner.

4.2 Patent pooling versus cross-licensing

A key feature of a patent pool, as compared with a cross-licensing agreement, is that the patent owners agree to license to third parties that do not themselves contribute patents to the pool. The decision to license the aggregated technology to third parties strikes us as being very similar to the decision to license a patent in the usual simple context where patent rights are not fragmented. On the one hand, licensing to third parties will bring royalty revenues. On the other hand, it may increase competition on products embedding the intellectual property of the licensors. There are clearly many technologies where the second effect (profit dissipation) outweighs the first (generation of royalty revenues).

Consider the example two pharmaceutical firms in possession of a patent on a novel drug but unable to produce and commercialize it without infringing each other's patent²⁷. The simplest solution to the blocking positions is a cross-licence which leads to a duopoly on the market. However, both firms can do better by buying or selling an exclusive license to the other firm; the resulting monopoly will be more profitable than the combined duopoly rents which allows for a bargaining surplus to be divided between the two firms. On the other hand, a patent pool would be worse than a cross-licence because allowing the entry of new firms further dissipate oligopoly rents faster than the royalty payments would rise. Therefore the most profitable option is the aggregation of rights by one firm, followed by a cross-licence and then a patent pool. If the aggregation of rights is not possible for antitrust or other reasons, then the cross-licence will be preferred to a pool.

²⁶ By aggregation of rights we mean the acquisition of exclusive licenses by one entity, for instance one of the patent owners.

²⁷ Our hypothetical might be the result of a patent race with two research groups submitting applications for different aspects of the same discovery.

We thus agree with Grassler and Capria (2003) who argue that for patents that cover components of downstream pharmaceuticals products, pooling is not attractive for patent holders. It is clear, however, that many life science patents are not directed to the actual therapeutic products but instead cover research tools that can be used to develop and test pharmaceutical products. It is in the aggregation of such research tools that patent pools may be helpful.

5. CONCLUSION

Our enquiry first attempted to clarify what a patent pool is. Despite ruling out non-voluntary patent pools and the idea of a unique collective rights organization, the answer turned out to be somewhat imprecise. Although patent pools have a common core (an agreement to license to third parties as a package), the term can cover different practices. One that we mentioned *en passant* but did not develop further is that the agreement could be made *ex ante* (i.e. before inventions have been made) between members of a research collaboration or consortium. Another which is much better known is the model of the MPEG patent pool which has been imitated by several others. We noted that the MPEG patent pool was an institution intimately linked to a technical standard and designed to facilitate technology licensing on a large scale. Although inspired by the examples of MPEG and DVD, the SARS patent pool and other biotechnology patents pool will in all likelihood represent a slightly different type of practice, in particular with respect to the form of the licensing terms.

The main reason for the interest in patent pools in biotechnology is that they could be an *ex post* practical solution to address fragmented intellectual property rights and anticommons effects that may arise from this fragmentation. We suggested that the formation of patent pools may lower total transaction costs by clarifying patent landscapes and reducing the number of necessary transactions. Pooling also modifies the repartition of transaction costs to the benefit of licensees and thus can be used by patent owners to render their technology more attractive.

We then briefly introduced the regulatory (i.e. antitrust) environment in which patent pools operate in Europe and in the United States. The central element of the antitrust analysis of patent pool is the nature of the relationship between pooled patents. Given the early stages of development of some technologies and the lack of standards, the requirement that all patents to be included in the pool should be essential may be difficult to meet for biotechnology patent pools as well as undo part of their rationale. A key factor for the future of patent pools in biotechnology is whether regulatory authorities will be ready either to accept a weaker version of the complementarity of underlying patents than essentiality or to develop special guidelines for biotechnology patent pools. It might for example be possible to design a safe harbour around a requirement that the patents in the pool can be licensed independently.

An important message that we developed in the last section of this paper is that patent pooling and independent licensing are not the only options available to owners of complementary patent rights and that the alternatives -i.e. aggregation of rights by one entity and cross-licensing- are particularly relevant in the context of biotechnology. The first reason is that in biotechnology exclusive use is often more profitable than licensing as a mode of intellectual property management. This implies that owners of patent rights will tend to prefer aggregation of rights by one entity and cross-licensing to pooling. The second reason is that universities and specialized research firms hold important portfolios

of patents, which facilitate the aggregation of rights since more patents can be expected to be available for exclusive licenses.

As a final point, we would like to place our discussion in the broader context of markets for technology. It is to be expected that the downside of patents and of their exclusionary power can be largely mitigated by the existence of a well-functioning market for technology. With such a market, patents rights can be transferred to those best placed to use them and they can be licensed to multiple entities. Unfortunately, it is not clear whether markets for technology indeed function well. Heller and Eisenberg (1998) have expressed a predominantly pessimistic view of markets for technology in biomedical research by emphasizing the costs of bundling rights, the heterogeneity of patent owners and cognitive biases. Other authors are more optimistic about markets for technology in biomedical research (e.g. Arora et al., 2001). Nevertheless, it is to be expected that information asymmetries and uncertainty over the value, breadth and validity of patents represent impediments to transactions between multiple patent owners. Given these market imperfections, it is clear that many mutually beneficial bilateral transactions that would otherwise be concluded do not happen, which ultimately is detrimental to innovation in biomedical research at large. Thus, there must be value in mechanisms and institutions that can facilitate transactions in the market for technology. Patent pools being such an institution may therefore have a role to play in biotechnology in the future despite the current obstacles to their use.

APPENDIX A: CONSOLIDATION OF PATENT RIGHTS IN REVERSE GENETICS

The technology

Reverse genetics is a new technique to develop influenza vaccines. One of its great advantages over the conventional method (via hen's eggs) is that it allows much quicker development which would be essential in the event of a pandemic. Reverse genetics can also be used to develop the inter pandemic flu vaccines (which has to be done again every year for the new flu season), but then that advantage fades because manufacturers have more time to develop the vaccine (Fedson, 2005).

Reverse genetics IPR

The reverse genetics technology was initially developed by Peter Palese of Mount Sinai School of Medicine and later refined by the same person ("Labs rush to cultivate bird flu vaccine. Reverse Genetics allows creation of weakened virus", 2004). Other refinements were developed by Yoshihiro Kawaoka of the University of Wisconsin and by Robert Webster of St. Jude Children's Hospital in Memphis (ibid.). The initial technology was licensed by Mount Sinai to Aviron and Medimmune acquired those rights when it purchased Aviron in 2002 (ibid.).

The IPR for reverse genetics were thus divided between four portfolios (Fedson 2005, "MedImmune Expands Patent Estate for Reverse Genetics with New Rights from Mount Sinai School of Medicine" 2005):

- *Medimmune Fundamental Reverse Genetics Portfolio (WO 91/03552) [i.e. the initial Mount Sinai technology]
- *Mount Sinai School of Medicine Plasmid Rescue Portfolio (WO 01/04333)
- *Wisconsin Alumni Research Foundation Plasmid Rescue Portfolio (WO 00/60050)
- *St. Jude Children's Research Hospital Dual Promoter Plasmid Rescue Portfolio (WO 01/83794)

Medimmune has recently acquired exclusive licenses first from the portfolio of Wisconsin and St. Jude and then from Mount Sinai School of Medicine ("Technology for Faster, Safer Development of Pandemic Flu Vaccine Licensed by Mount School of Medicine" 2005; "MedImmune Expands Patent Estate for Reverse Genetics with New Rights from Mount Sinai School of Medicine" 2005).

Conclusion

The IPR situation described above was arguably a classical case of a patent thicket with fragmented intellectual property rights as well as uncertainty about who owns the technology. A patent pool might have been an option and indeed the question of a patent pool for this technology was raised (Fedson 04). Instead, the situation was resolved by one patent owner acquiring exclusive licenses from the other ones. Note that Medimmune is vertically integrated biotechnology firm and the other patent owners were academic institutions.

APPENDIX B: THE FOUR WELL-KNOWN POOLS IN THE MODERN ERA

Technology	Administrator	Year of formation	Members
MPEG-2 Digital Video Digital standard for video compression	MPEG LA	1997	Alcatel, Canon, CIF Licensing, Columbia University, France Télécom, Fujitsu, General Instrument, GE Technology Development, Hitachi, KDDI Corporation, LG Electronics, Matsushita, Mitsubishi, Nippon Telegraph and Telephone Corporation, Philips, Robert Bosch GmbH, Samsung, Sanyo Electric, Scientific Atlanta, Sharp, Sony, Thomson Licensing, Toshiba, and Victor Company of Japan.
DVD (3C)	Philips	1998	Philips, Sony, Pioneer
DVD (6C)	DVD 6C licensing agency	1999	Hitachi, Matsushita, Mitsubishi Electric, Time Warner, Toshiba, Victor Company of Japan
3G Platform Third generation mobile phones	3G Patents Limited	2001	Alcatel, Bosch, Cegetel, the Electronics and Telecommunications Research Institute, France Telecom, Fujitsu, KPN, Korea Telecom, LG Telecom, Matsushita Electric Industrial, Mitsubishi Electronic Corp., NEC, NTT DoCoMo, Samsung Electronics, Siemens, SK Telecom, Sonera, Sony, and Telecom Italia Mobile

Sources. <http://www.mpegla.com>; <http://www.3gpatents.com>; <http://www.dvd6cla.com/>; <http://www.licensing.philips.com/licensees/conditions/dvd/>

REFERENCES

- Letter from Charles James to Ky Ewing, November 12, 2002. [3G Letter].
- Letter from Joel Klein to Carey Ramos, 10 June 1999. [Toshiba Letter].
- Letter from Joel Klein to Garrard Beeney, December 16, 1998. [Sony Letter].
- Letter from Joel Klein to Gerrard Beeney, 26 June 1997. [MPEG Letter].
- “Labs rush to cultivate bird flu vaccine. Reverse Genetics allows creation of weakened virus” (2004) San Francisco Chronicle.
- “Technology for Faster, Safer Development of Pandemic Flu Vaccine Licensed by Mount School of Medicine”. (2005) Mount Sinai Press Office.
- “MedImmune Expands Patent Estate for Reverse Genetics with New Rights from Mount Sinai School of Medicine” (2005). PR Newswire.
- AGRAWAL, A. & GARLAPPI, L. (2002) Public Sector Science and the 'Strategy of the Commons' (Abridged). *Best Paper Proceedings, Academy of Management*.
- AOKI, R. & NAGAOKA, S. (2004) The Consortium Standard and Patent Pools. *The Economic Review*, 55, 346-56.
- AOKI, R. & NAGAOKA, S. (2005) Coalition formation for a consortium standard through a standard body and a patent pool: theory and evidence from MPEG2, DVD and 3G. *Institute of Innovation Research Working Paper*, 05.
- ARORA, A.; FOSFURI A. AND GAMBARDILLA, A. (2001) *Markets for technology; the economics of innovation and corporate strategy*, Cambridge, MA, The MIT Press.
- BEENEY, G. (2002) Pro-Competitive Aspects of Intellectual Property Pools: A Proposal for Safe Harbor Provisions.
- BIO (2002) Testimony of the Biotechnology Industry Organization on Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy before the Federal Trade Commission and the Department of Justice.
- CARLSON, S. (1999) Patent pool and the antitrust dilemma. *Yale Journal of Regulation*, 16, 359-98.
- CHOI, J. P. (2002) Patent Pools and Cross-Licensing in the Shadow of Patent Litigation. *CesInfo Working Paper*.
- COCKBURN, I. (2003) O Brave New Industry, That Has Such Patent in It! Reflections On the Economics of Genome Patenting. IN KIEFF, F. (Ed.) *Perspectives on properties of the human genome project*. Academic Press.

- COCKBURN, I. (2004) The Changing Structure of the Pharmaceutical Industry. *Health Affairs*, 23, 10-22.
- EBERSOLE, T.; GUTHRIE, M. AND GOLSTEIN, J. (2005) Patent pools and standard setting in diagnostic genetics. *Nature Biotechnology* 23(8):937-938.
- EUROPEAN COMMISSION (2004) Guidelines on the application of article 81 of the EC Treaty to technology transfer agreements. *Official Journal*, C 101. [EC Guidelines].
- FEDERAL TRADE COMMISSION (2003) To Promote Innovation: The Proper Balance Of Competition Law and Policy. A Report by the Federal Trade Commission.
- UNITED STATES DEPARTMENT OF JUSTICE AND FEDERAL TRADE COMMISSION (1995) Antitrust Guidelines for the Licensing of Intellectual Property [US Guidelines].
- FEDSON, D. (2004) Vaccine Production and Pandemics: Reverse Genetics IP and Pandemic Influenza Vaccination. Presentation at the meeting "High Tech IP Issues in a Global Marketplace" Stanford Law School, May 17-18.
- FEDSON, D. (2005) Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development. *Journal of Public Health Policy*, 26, 4-29.
- GILBERT, R. (2004) Antitrust for Patent Pools: A Century of Policy Evaluation. *Stanford Technology Law Review*.
- GOLD, R. (2003) SARS Genome Patent: Symptom or Disease ? *The Lancet*, 361, 2002-3.
- GRASSLER, F. & CAPRIA, M. A. (2003) Patent pooling: Uncorking a technology transfer bottleneck and creating value in the biomedical research field. *Journal of Commercial Biotechnology*, 9, 111-8.
- HELLER, R. & EISENBERG, R. (1998) The Anticommons in Biomedical Research. *Science*, 280, 698-701.
- HORN, L. (2003) Alternative approaches to IP management: One-stop technology platform licensing. *Journal of Commercial Biotechnology*, 9, 119-27.
- ESSENTIAL INVENTIONS (2005) Essential Patent Pool for AIDS: Background Information.
- JANIS, M. (2005) Aggregation and Dissemination Issues in Patent Pools. IN COLLISON, W. (Ed.) *Issues in Competition Law and Policy*. ABA.
- KLEIN, J. (1997) An Address to the American Intellectual Property Law Association, on the Subject of Cross-Licensing and Antitrust Law.
- LEMLEY, M. & SHAPIRO, C. (2005) Probabilistic Patents. *Journal of Economic Perspectives*, 19, 75-98.
- LERNER, J. & TIROLE, J. (2004) Efficient Patent Pools. *American Economic Review*, 94, 691-711.

- LERNER, J., TIROLE, J. & STROJWAS, M. (2005) The Design of Patent Pools: The Determinants of Licensing Rules. *NBER Working Paper*.
- MERGES, R. (2001) Institutions for Intellectual Property Exchange: The Case of Patent Pools. IN DREYFUSS, R. (Ed.) *Intellectual Products: Novel Claims to Protection and Their Boundaries*. Oxford University Press.
- RESNIK, D. (2003) A Biotechnology Patent Pool: An Idea Whose Time Has Come? *Journal of Philosophy, Science and Law*, 3.
- SEIDE, R., LECOINTE, M. & GRANOVSKY, A. (2001) Patent Pooling in the Biotechnology Industry. *Licensing Journal*, 27, 28-9.
- SHAPIRO, C. (2001) Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard Setting. IN JAFFE, A., LERNER, J. & STERN, S. (Eds.) *Innovation Policy and the Economy*. Cambridge, MA, MIT Press.
- SIMON, J. (2004) How Patents May Affect the Development of a SARS Vaccine: The Possible Role of Patent Pools.
- SIMON, J., ET AL. (2005) Managing severe acute respiratory syndrome (SARS) intellectual property rights: the possible role of patent pooling. *Bulletin of the World Health Organization*, 83, 707-10.
- SUNG-HWAN, K. (2004) Vertical Structure and Patent Pools. *Review of Industrial Organization* 25, 231-50.
- USPTO (2000) Patent Pools: A Solution To The Problem of Access to Biotechnology Patents ? United States Patents and Trademark Office.
- WALSH, J.; ARORA, A.; COHEN, W. (2003) Research Tool Patenting and Licensing and Biomedical Innovation. IN COHEN, W. & MERILL., S. (Ed.) *Patents in the Knowledge-Based Economy*. Washington, DC, National Academies Press.
- WHO (2003) Report of WHO Consultation on Needs and Opportunities for SARS Vaccine Research and Development. Geneva, World Health Organization.
- WHO (2005) Genetics, genomics and the patenting of DNA: Review of potential implications for health in developing countries, Geneva, World Health Organization, Human Genetics Program.
- WHO (2006) Public health, Innovation and Intellectual Property Rights. Report of the Commission on Intellectual Property Rights, Innovation and Public Health. Geneva, World Health Organization.